JAN - 6 2010

510(k) SUMMARY

The following 510(k) summary is being submitted as required by

Submission Information

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Sponsor:	34-6 Keumam-ri, Seotan-myeon, Pyeongtaek, Gyeonggi-do, 451-852 Republic of Korea
Date Prepared:	May 5, 2009

Device Identification

Trade Name:	4CIS® PEEK PLIF Cage System
Common/Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device – lumbar 21 CFR Section 888.3080 MAX Class II

Substantially Equivalent Predicate Legally Marketed Devices

Device Description

The subject device, 4CIS® PEEK PLIF Cage System is made of devices for fixation of spine. This system allows maximum preservation of bony endplate and vertical square teeth ensure enough contact surfaces with bony endplate, which prevents "sinking-in" of cage into the vertebral body, while vertical teeth increase the anchoring and prevent slipping. It has two tantalum markers for ease of visualization on radiographs.

The components are manufactured from PEEK-OPTMA LT1 (Polyetheretherketone, ASTM F2026) material.

Indications for Use

The 4CIS PEEK PLIF IBF Device is an intervertebral body device intended for use skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with up to Grade 1 Spondylolisthesis at one or two contiguous levels from L2-S1. DDD is defined as discogenic pack pain with degeneration of the disk confirmed by history and radiographic studies. 4CIS Peek PLIF IBF devices are intended to be used with autologous bone graft to facilitate fusion. The device is to be used in patients who have had six months of non-operative treatment.

The 4CIS PEEK PLIF IBF devices are to be implanted via a direct posterior approach. The device is implanted singly or in pairs, with supplemental fixation.

Performance Data

Mechanical testing as listed in **APPENDIX 10**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Solco Biomedical Co., Ltd.
% Solco USA, Inc.
Mr. Saeyoung Ahn
Official Correspondent
155 Gibbs Street, Suite 510
Rockville, Maryland 20850

JAN - 6 2010

Re: K092162
Trade/Device Name: 4CIS® PEEK PLIF Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MAX
Dated: December 23, 2009
Received: December 24, 2009

Dear Mr. Ahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092162

Device Name: 4CIS PEEK PLIF Cage System

Indications For Use:

The 4CIS® PEEK PLIF is intervertebral body fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. 4CIS® PEEK PLIF ™ IBF device is intended to be used with autologous bone graft to facilitate fusion. The 4CIS® PEEK PLIF ™ IBF device is to be used in patients, who have had six months of non-operative treatment. The device is to be implanted via a direct posterior approach. The 4CIS® PEEK PLIF ™ device may be implanted singly or in pairs in the lumbosacral spine with supplemental fixation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092162